

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST)	
LABORATORIES HOLDINGS, LTD.,)	
CEREXA, INC., TAKEDA)	
PHARMACEUTICAL COMPANY)	
LIMITED and ALLERGAN USA, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 15-018 (GMS)
)	CONSOLIDATED
APOTEX CORP., APOTEX INC.,)	
)	
Defendants.)	

PLAINTIFFS' ANSWERING CLAIM CONSTRUCTION BRIEF

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Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Cerexa, Inc., Takeda Pharmaceutical Company Limited, and Allergan USA, Inc. (collectively, "Plaintiffs") respectfully submit this answering brief in further support of their proposed claim constructions.

I. INTRODUCTION

Plaintiffs' proposed claim constructions are firmly grounded in the intrinsic evidence and wholly consistent with governing precedent. Defendants, in contrast, propose constructions that are inconsistent with the intrinsic evidence and unsupported by their cited cases. For all these reasons, as explained in detail below, Plaintiffs respectfully request that the Court adopt their proposed claim constructions and reject Defendants' proposed constructions.

II. THE DISPUTED CLAIM TERMS

A. The '175 Patent

1. "a compound of the formula. . . its salt or its reactive derivative; wherein each symbol has the meaning given in claim 1"

Claim 14 is directed to a method of making the compounds of the invention, including ceftaroline fosamil, the active ingredient in Teflaro.¹ Claim 14 describes reacting together two intermediate compounds that have two different skeleton formulae, using the definitions (or "symbols") set forth in Claim 1 for the variables Q, R¹, and R². The claimed reaction of these two intermediate compounds produces one of the genus of compounds described in Claim 1, for example, ceftaroline fosamil.

Plaintiffs and Apotex previously disputed two aspects of the construction for the second skeleton formula shown in Claim 14. Notably, in its opening brief, Apotex did not address the first aspect of the construction: Plaintiffs' inclusion of the phrase "the genus defined by" in their

¹ After Plaintiffs amended their infringement contentions against Apotex to add Claim 14 of the '175 patent and filed their opening claim construction brief, Apotex produced additional documents showing its infringement of this claim. Plaintiffs have amended their infringement contentions against Apotex to include this newly produced material. (D.I. 112.)

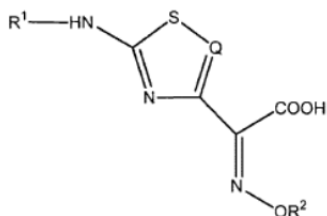
proposed construction of this term. As such, Apotex appears to have waived any dispute on this aspect of the construction.

As to the second aspect of the construction, Plaintiffs and Apotex dispute the meaning of the claim term "reactive derivative." Plaintiffs argue that the term should be afforded its plain meaning. In contrast, Apotex seeks to limit "reactive derivative" to just one type of reactive derivative – an "activated carbonyl derivative" – and exclude all other reactive derivatives. But the plain meaning of "reactive derivative" is not so limited.

In its opening brief, Apotex seeks to import a limitation into the claim by replacing the phrase "or its reactive derivative" with the much narrower phrase "or activated carbonyl derivative thereof." But the terms "activated carbonyl" and "activated carbonyl derivative" appear nowhere in the intrinsic evidence, making it difficult to understand how Apotex can argue for a definition or disavowal under *Thorner*. Apotex argues that a person of ordinary skill would believe that "there is no other way" to read the claim and that the synthetic examples of the '175 patent all disclose the use of an activated carbonyl group. (Def. Br. at 13.) But there is no intrinsic evidence support for the former argument, and the latter argument seeks to limit the plain and ordinary meaning of the claim language to specification embodiments in violation of governing precedent. *See, e.g., Inline Plastics Corp. v. EasyPak, LLC*, 799 F.3d 1364, 1368-9 (Fed. Cir. 2015) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.")).

As its final argument, Apotex points to the prosecution history of the '175 patent. But the prosecution history does not support restricting the plain and ordinary meaning of "reactive derivative." Indeed, Claim 14 was amended only once during prosecution, and the meaning of

the claim term "reactive derivative" was not the subject of that amendment. ('175 patent prosecution history ("PH"), 1/22/2002 Response After Final Action at 4, 7.) Specifically, the claim term "reactive derivative" appeared in both the original version of the claim and the amended version; the claim term was moved, but its meaning was not changed in any way by the amendment and was not the subject of any argument. ('175 patent PH, 1/22/2002 Response After Final Action at 7.) The amendment is shown below:



its salt or its reactive derivative;

wherein each symbol has the meaning given [above, its salt or its reactive derivative, if necessary,] in claim 1

[followed by converting R¹ to a phosphono group].

('175 patent PH, 1/22/2002 Response After Final Action at 7 (with the standard convention of underlining added text and bracketing removed text).)

The applicants described the amendment as follows: "By this amendment, R¹ has been limited to a phosphono group in claim 1, and esters have been removed from claims 1, 12, 13, and 14." ('175 patent PH, 1/22/2002 Response After Final Action at 8.) The applicants pointed to the removal of "esters" from claim 14, but did not amend, much less limit, the claim term "reactive derivative."² No amendment defined or disclaimed any aspect of the plain meaning of "reactive derivative," and Apotex's arguments fail accordingly.

² Notably, the term "esters" was removed from a completely different part of claim 14 – the portion of the claim relating to the first intermediate, which is not at issue here. ('175 patent PH, 1/22/2002 Response After Final Action at 7.) The removal of the term esters is therefore wholly unrelated to the construction of the claim term "reactive derivative."

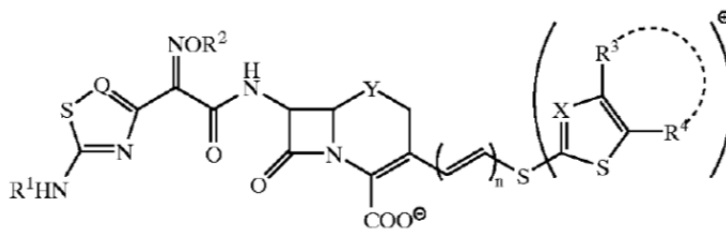
Apotex's insistence regarding the " R^1 " group is misplaced. The applicants nowhere suggested that the limitation of R^1 to a phosphono group in claim 1 (referenced in the amended claim 14) limited the scope of the phrase "reactive derivative." As such, the prosecution history falls far short of the "clear and unmistakable" disavowal required to find a disclaimer. *See, e.g., Avid Technology, Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016).

For all these reasons, Plaintiffs respectfully submit that their proposed construction should be accepted and Apotex's proposed construction should be rejected.

2. "the compound shown in claim 1" and "the compound of claim 4"

Plaintiffs' proposed constructions are consistent with the plain and ordinary meaning of the terms, as construed in light of the intrinsic evidence and the parties' agreed constructions. Indeed, in its haste to argue that these claim terms are indefinite, Apotex fails to address the parties' agreed construction of Claim 1.

Claim 1 describes "A compound" having the following skeleton formula:



In their joint submission to the Court, the parties agreed that "[a] compound of the formula" in Claim 1 means "[a] compound within the genus defined by the formula" shown in Claim 1. (D.I. 102 at Exhibit A, page 1.) Consistent with this agreement, Apotex states in its opening brief that "the three independent claims recite a genus of cephem compounds or individual members of that genus." (Def. Br. at 9.) Given this agreement by the parties, as confirmed by the intrinsic evidence, Claim 1 includes a genus of compounds defined by the depicted skeleton formula.

Claim 17 refers back to "the compound shown in Claim 1." Claim 17, therefore, refers back to the agreed genus of compounds defined by the skeleton formula of Claim 1.

While ignoring the parties' agreement, Apotex also fails to address the governing precedent supporting Plaintiffs' proposed construction. As the Federal Circuit has explained, the indefinite article "a" can be interpreted either as singular or plural. *See Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1343 (Fed. Cir. 2008). In connection with Claim 1, the parties have agreed, as set out in the Final Second Amended Joint Claim Construction Chart, that the indefinite article "a" is plural: "A compound within the *genus* defined by the formula," where "genus" refers to a group of compounds. (D.I. 102 at Exhibit A, page 1(emphasis added).) The Federal Circuit has explained that where a claim uses a definite article ("the") to refer back to an antecedent indefinite article ("a"), the subsequent reference to the claim element should be interpreted consistently with the interpretation of the initial claim element. *See Baldwin*, 512 F.3d at 1343. Here, the definite article ("the") in Claim 17 refers back to the initial indefinite article ("a") in Claim 1 ("A compound of the formula"). The person of ordinary skill in the art would therefore understand the phrase "the compound" in Claim 17 to refer back to one of the compounds within the genus defined by the skeleton formula shown in Claim 1.

For similar reasons to those discussed above, Plaintiffs' proposed construction of "the compound of claim 4" is consistent with the plain and ordinary meaning of the term interpreted in light of the intrinsic evidence, and is also fully supported by governing precedent.

For all these reasons, Plaintiffs respectfully submit that their proposed construction of these terms should be accepted.

3. "A method for treating a bacterial infection"

As the Federal Circuit has explained, when "limitations in the body of the claim rely on and derive antecedent basis from the preamble, then the preamble may act as a necessary

component of the claimed invention." *See, e.g., Pacing Technologies, LLC v. Garmin International, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) (internal citation omitted); *Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372-73 (Fed. Cir. 2014). Here, the preamble provides antecedent basis for two limitations in the body of the claims. First, the preamble phrase "treating a bacterial infection" provides antecedent basis for the limitation "to a patient suffering from *the* bacterial infection" (emphasis added). Indeed, the phrase "the bacterial infection" in the body of the claim refers directly back to the phrase "a bacterial infection" in the preamble. Second, the preamble provides antecedent basis for the limitation "effective amount." When read with the preamble, the meaning of "effective amount" is manifest – an amount effective to treat a bacterial infection. Given that it provides antecedent basis for two limitations in the body of the claim, the disputed preamble language is limiting. *See, e.g., Pacing Technologies*, 778 F.3d at 1024; *Proveris*, 739 F.3d at 1372-73; *see also Sanofi v. Glenmark Pharms., Inc.*, 14-cv-264, 2015 WL 5092631, at *5 (D. Del. Aug. 28, 2015) (construing a similar preamble as limiting on the grounds that the preamble provided antecedent basis for two later claim elements, one in the same claim and one in a dependent claim).

Apotex relies on cases that are inapposite because – unlike the case at bar – they address preamble language that does not provide an antecedent basis for the body of the claims. *See, e.g., Teva Pharmaceuticals USA, Inc. v. Forest Labs., Inc.*, 13-cv-2002, 2015 WL 4143277, at *2 n.3 (D. Del. Jul. 9, 2015) (stating that "[t]he preamble phrase does not . . . serve as an antecedent basis for subsequent elements in the claim body"); *L'Oreal S.A. v. Johnson & Johnson Consumer Companies*, 12-cv-98, 2013 WL 3788803, at *1, n.2 (D. Del. Jul. 19, 2013) (stating that "nothing in the disputed phrase serves as an antecedent basis for later terms"); *U.S. Philips Corp. v. Eastman Kodak Co.*, 06-cv-251, 2008 WL 5732133, at *2, n.19 (D. Del. Jan. 25, 2008) (finding

that a phrase "merely states a purpose of the claimed method," where the phrase did not provide antecedent basis for other terms in the body of the claim).³

In fact, in one case relied on by Apotex, this Court found language in a preamble limiting on the grounds that the claimed method's first step "expressly incorporates by reference this preamble term." *U.S. Philips Corp*, 2008 WL 5732133, at *2, n.15 (noting that "[t]his incorporated term is thus 'intimately enmeshed with the ensuing language in the claim' (internal citation omitted), and accordingly limits the claim's scope. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1305–06 (Fed.Cir. 2005) (holding that limitations in claim preamble provided antecedent basis for limitations in claim body and therefore constituted limitations on claim)").

An independent reason to construe a preamble as limiting exists when the preamble recites particular structure or steps that are highlighted as important by the specification. *See Proveris*, 739 F.3d at 1372. Here, the specification of the '175 patent is directed to treating bacterial infections, and highlights the effectiveness of the claimed compounds when used to treat such infections, including drug-resistant infections such as those caused by MRSA. Apotex asserts that "the specification mentions possible uses for the compounds only in passing." (Def. Br. at 10.) But that assertion is flatly contradicted by the specification itself. For example, the specification states:

The cephem compound (I) has ***a broad antibacterial spectrum and an excellent antibacterial activity against Gram-negative bacteria and Gram-positive bacteria including Staphylococcus aureus and MRSA***, and is ***useful for treatment or prevention of infectious diseases caused by these bacteria***.

³ Apotex also incorrectly relies on *In re Copaxone 40 Mg Consolidated Cases*, where this Court found preamble terms to be non-limiting that merely "list[ed] the intended outcome from following the claimed steps," "duplicate[d] the dosage requirements," and/or did not "provide any additional required structure or condition for the claims." *In re Copaxone 40 Mg Consolidated Cases*, 14-cv-1171, 2016 WL 873062, at *1 n.2 (D. Del. Mar. 7, 2016). The Court pointed to preamble terms, unlike the terms at issue here, that were duplicative of language in the body of the claim and/or did not provide antecedent basis for the body of the claim. *See id.*

'175 patent, Col. 30:15-20 (emphases added). Indeed, the specification repeatedly emphasizes the "treatment" of bacterial infections:

The *pharmaceutical composition of the present invention* which may contain pharmaceutically acceptable carriers, diluents, bulking agents, etc., mentioned above *contains an effective amount* of Compound (I) of the present invention *for the treatment and prevention of bacterial infectious disease*.

'175 patent, Cols. 25:63-26:1 (emphases added). The preamble thus recites a step highlighted as important by the specification: "treating a bacterial infection." It should be construed as limiting.

Apotex argues against construing the disputed preamble language in the '175 patent mainly by misstating the parties' agreement regarding the preamble language in the '400 patent. (Def. Br. At 8.) Contrary to Apotex's assertions, there is no inconsistency in Plaintiffs' positions.

With respect to the '400 patent, Claim 19 states:

A method of treating a bacterial infection comprising administering *to a patient in need thereof* a pharmaceutical composition according to claim 7 wherein the bacterial infection is selected from the group consisting of community acquired bacterial pneumonia and bacterial skin and skin structure infections and the pharmaceutical composition comprises 600 mg ceftaroline fosamil.

To narrow and focus the claim construction disputes before this Court, Plaintiffs agreed to a compromise with Apotex regarding the preamble of claims 10-11 and 13-23 of the '400 patent. Specifically, in exchange for Apotex agreeing to construe the phrase "to a patient in need thereof" as "to a patient suffering from a bacterial infection," Plaintiffs agreed not to argue that the preambles to claims 10-11 and 13-23 of the '400 patent are limiting. (D.I. 102 at 5-6.) This compromise agreement for the '400 patent is reflected in the parties' joint claim construction statement. (D.I. 102 at 5-6.)

By their compromise agreement, the parties clarified that the body of the claims in the '400 patent require treating a bacterial infection in a patient with the claimed pharmaceutical composition. By their compromise agreement, the parties also eliminated the need for the preambles of claims 10-11 and 12-23 of the '400 patent to provide antecedent basis for the body

of the claims. Specifically, construing the phrase "to a patient in need thereof" as "to a patient suffering from *a bacterial infection*" eliminates the reference to an antecedent basis (the creation of the "need thereof," *i.e.*, a bacterial infection). Construing the claim term as "to a patient suffering from *a bacterial infection*" also provides an antecedent basis for the subsequent references to "the bacterial infection" in the body of the claims. Stated another way, the parties' agreement regarding the preamble language in the '400 patent has the same effect as construing the preamble language "treating a bacterial infection" in the '400 patent as limiting, because it adds "suffering from a bacterial infection" to the construction of "to a patient in need thereof" who is administered the claimed composition in the body of the claims.

The parties' agreement regarding the preamble language in the '400 patent is perfectly consistent with Plaintiffs' arguments regarding the '175 patent. If anything, the parties' agreement regarding the '400 patent highlights the inconsistency of Apotex's positions. Indeed, although the parties agreed to a compromise for the '400 patent, Apotex inexplicably rejected a similar compromise offered by Plaintiffs regarding the '175 patent.

For all these reasons, Plaintiffs respectfully submit that the preambles of Claims 5-7, 12, 15-16, and 20-21 of the '175 patent should be construed as limiting.

B. The '400 Patent

1. (6R,7R)-7-[[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

In their opening brief, Defendants do not dispute that the inventors acted as their own lexicographers to define the compound described in claims 3-9 and 13-23 as "Compound A." Nor do they dispute that the applicants referred to this chemical compound as "Compound A" throughout the specification. *See e.g.*, '400 patent at 4:40-56; 6:59-7:50; 20:20-27:67. Indeed,

Defendants provide no principled reason for refusing to include the term "Compound A" as part of the construction.

Contrary to Defendants' arguments (Def. Br. at 18), Plaintiffs are not asking this Court to construe the term "Compound A." Instead, Plaintiffs are asking the Court to confirm the intrinsic evidence and construe the long chemical name in the claims as either the parties' agreed chemical structure or "Compound A." Including "Compound A" in the construction would aid the parties and the Court as the case proceeds. Indeed, there will be numerous times when the parties ask the Court to consider the specification evidence regarding Compound A during this case, and there is no need for the ambiguity Defendants seek to inject by removing "Compound A" from the construction.

For all these reasons, Plaintiffs respectfully submit that their proposed construction of this term should be adopted.

2. "up to about"

As stated in their opening brief, Plaintiffs dispute any assertion of indefiniteness regarding the claim term "up to about," but in conformity with this Court's precedent and practice, Plaintiffs will not address the alleged indefiniteness until the appropriate time under the Court's schedule. In the interim, the parties have proposed the same construction for this claim term, which Plaintiffs respectfully request that the Court adopt, without prejudice to any indefiniteness argument Defendants may present under the Court's schedule.

III. CONCLUSION

For all the reasons set forth above and in their opening brief, Plaintiffs respectfully request that the Court adopt their proposed constructions of the claim terms in dispute.

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September 9, 2016

CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 9, 2016, upon the following in the manner indicated:

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